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GUIDE FOR QUANTIFYING LABORATORY SUPPLIES

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DELIVER
No Product? No Program. Logistics for Health

GUIDE FOR QUANTIFYING LABORATORY SUPPLIES

DELIVER
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Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID's central contraceptive management information system.

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Abstract
Laboratory commodities are used to provide preventive and care services that support public health programs, such as HIV/AIDS, tuberculosis, and malaria. Without adequate laboratory supplies or an effective supply chain to deliver the commodities to facilities on a continuous basis, investments in provision of these services will not be maximized. The specific characteristics and quantities of laboratory commodities to be handled pose a particular challenge to managing the supply chain. Quantification of health commodities is a process that includes estimating the quantities and the cost of products required to meet customer demand, and to fill the pipeline with adequate stock levels, taking into account service delivery capacity, supply pipeline requirements, and resources available for procurement. The primary focus and purpose of this guide is to describe the process and the methodologies used for quantifying laboratory commodities.

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ACRONYMS

ABC	analysis for classification using A, B, C
AFB	acid-fast bacilli
AIDS	acquired immune deficiency syndrome
ALT	alanine aminotransferase
AMQR	average monthly quantity required
ART	antiretroviral therapy
ATLAS	Assessment Tool for Laboratory Service
BMS	British Medical Society
CBC	complete blood count
CD4/CD8	cluster of differentiation (ratio of CD4 Cells to CD8 cells)
CDC	Centers for Disease Control and Prevention
CSF	cerebrospinal fluid
CO2	carbon dioxide
EDTA	ethylenediaminetetraacetic acid
ELISA	enzyme linked immunosorbent assay
FDA	Food and Drug Administration
g	gram
GLP	good laboratory practices
GPR	general purpose reagent
Hb	hemoglobin
HIV	human immunodeficiency virus
HMIS	health management information system
HVS	high vaginal swab
KOH	potassium hydroxide
LMIS	logistics management information system
mL	milliliter
MOH	ministry of health
MTB	Mycobacterium tuberculosis
NGO	nongovernmental organization
NPHLS	national public health laboratory services
OI	opportunistic infection
p24	protein 24 antigen
PCR	polymerase chain reaction
PEPFAR	President's Emergency Plan for AIDS Relief
pH	potential hydrogen, measure of acidity
PMTCT	prevention of mother-to-child transmission

QA	quality assurance
QC	quality control
RNA	ribonucleic acid
RPR	rapid plasma reagin
RT	room temperature
SGOT	serum glutamic oxaloacetic transaminase (AST)
SGPT	serum glutamic pyruvic transaminase (ALT)
SOH	stock on hand
SOP	standard operating procedures
STI	sexually transmitted infection
TB	tuberculosis
TPHA	Treponema pallidum hemagglutination assay
TPPA	Treponema pallidum particle agglutination
VCT	voluntary counseling and testing
VDRL	Venereal Disease Research Laboratory test
VEN	vital, essential, nonessential
WHO	World Health Organization
ZN	Ziehl-Neelsen

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PREFACE

It has been recently recognized that the quality of HIV/AIDS, tuberculosis (TB), and malaria programs is jeopardized by the lack of attention given to the key supportive components, such as laboratory services. Further exacerbating the quality of those programs is that weak health commodity supply chains have failed to ensure a reliable supply of the products at service delivery sites especially with the current rapid service expansion such as in HIV/AIDS programs.

A significant number of public sector programs in resource-poor countries urgently need enhanced capacity in quantification, financing, procurement, and delivery of laboratory commodities. Hence, global efforts to coordinate quantification, financing, and procurement are critical and must complement country-based initiatives.

Laboratory commodities are used in the provision of preventive and care services supporting public health programs. Without adequate laboratory supplies or without an effective supply chain to deliver the commodities to facilities on a continuous basis, investments in provision of those services will not be maximized.

The specific characteristics and the quantities of laboratory commodities to be handled pose particular challenges for managing the supply chain. The management of laboratory commodities is extensively discussed in the manual *Guidelines for Managing the Laboratory Supply Chain* (DELIVER 2006). This guide for quantifying laboratory supplies focuses on describing the process and the methodologies used for quantifying laboratory commodities.

This guide for quantifying laboratory commodities draws from the collective experience of DELIVER logistics advisors who have been involved in a range of activities to improve management of the supply chains for laboratory commodities in countries such as Ghana, Kenya, and Uganda. DELIVER's experience indicates that two of the most critical supply chain interventions regarding laboratory commodities at this time are as follows:

- Establish robust data collection and reporting systems to improve the availability and quality of data on laboratory commodities.
- Build capacity in quantification of laboratory commodity requirements at the country and program level to enhance informed decision making regarding financing and procurement of commodities, thus maximizing opportunities for continuous product availability in a country.

The DELIVER experience and lessons learned in quantification of laboratory commodities have been incorporated into the step-by-step approach to quantification presented in this guide. It is important to recognize that each country, each program, and each quantification will be unique as programs mature, as technologies and clinical practice evolve, and as management information systems improve to enable more evidence-based quantifications. This guide is, therefore, a work in progress that will be reviewed and updated over time to reflect the growing body of knowledge and best practices in supply chain management for laboratory commodities.

INTRODUCTION TO QUANTIFICATION

Quantification of health commodities is a process that includes estimating the quantities and the cost of products as required to meet customer demand and to fill the pipeline with adequate stock levels. The process takes into account the service delivery capacity, supply pipeline requirements, and resources available for procurement. Quantification consists of four distinct steps: forecasting demand, estimating requirements, calculating the costs for procuring the requirements, and, if needed, adjusting the final quantities to procure according to the amount of funding available.

The results of a quantification may be used (a) to calculate specific order quantities and to plan shipment schedules for short-term procurement planning, and (b) to assist in medium- to long-term program planning and resource mobilization efforts.

DEFINITION OF TERMS

Given the level of precision required to conduct accurate quantifications, it is important to clarify the use of specific terms within the context of this document that may be used and understood differently in other contexts.

CUSTOMER

Within the context of quantification of health commodities, the customer is the end user who is understood to be the patient, the client, or the provider who will ultimately receive, use, or consume the product within the forecast period.

CUSTOMER DEMAND

Therefore, customer demand refers to the specific quantities of the product to be dispensed or used to be able to meet customers' requests or their actual rather than their potential demand for health services within the forecast period.

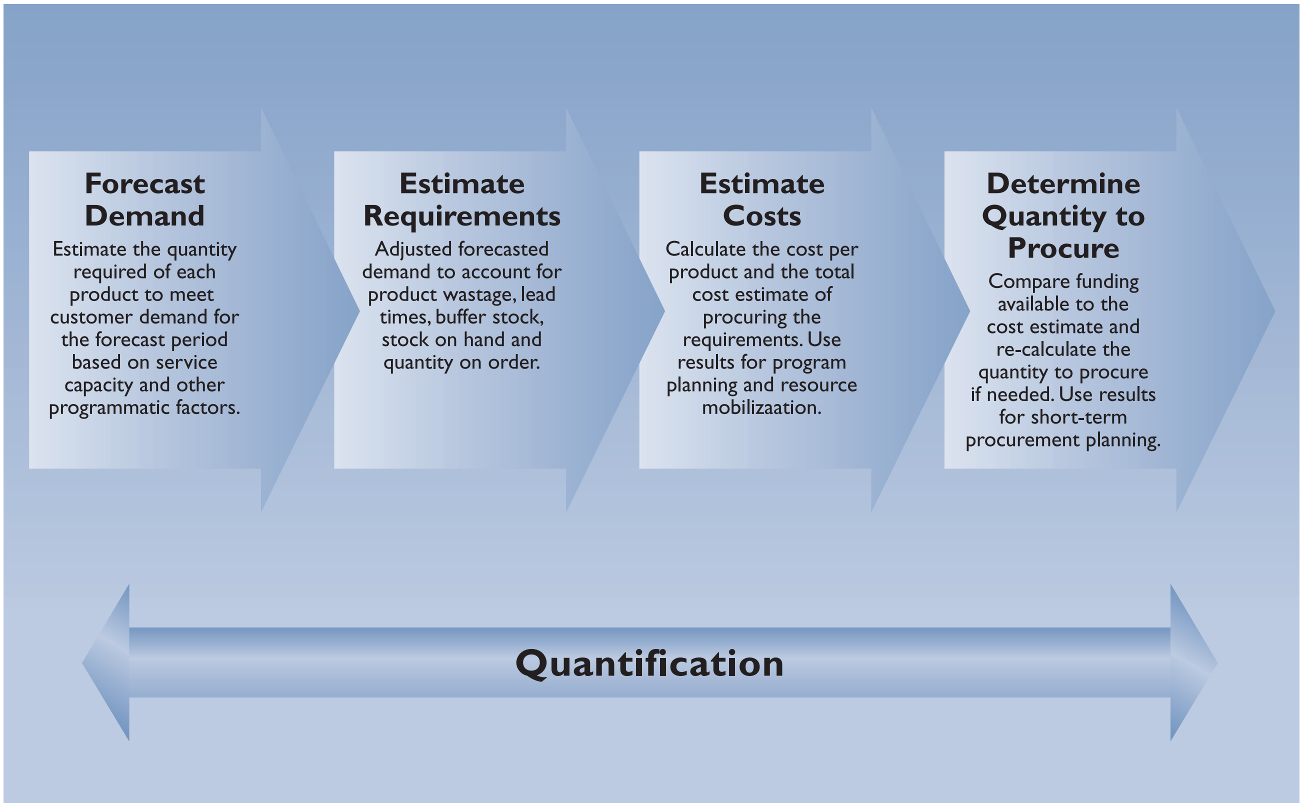
PRODUCT WASTAGE

Product wastage is the estimated quantity of product that is expected to be wasted through normal usage or through nonuse. Wastage through normal use or nonuse can occur, for example, through spillage, through incorrect measurement or damage during use, or by accounting for quantities of a product that may be returned by patients and that cannot be re-used or dispensed to other patients. Product wastage is based on an accepted standard percentage of total product consumption.

STEPS IN QUANTIFICATION

Figure 1 represents the steps in the quantification process.

Figure 1. The Quantification Process



FORECASTING DEMAND

Forecasting demand means estimating the quantity of products (e.g., drugs to be dispensed, HIV tests or laboratory reagents to be used) to meet customer demand for a future period of time. For health commodities, the number of customers to be served and the cases to be treated, along with the forecasted demand, may need to be adjusted to reflect (a) the scope of the quantification, which may be a national-level quantification or may be for a specific program, service sector, geographic region, level of service, or patient target group; (b) the purpose of use within the quantification (for example, drugs for both antiretroviral therapy [ART] and prevention of-mother-to- child transmission [PMTCT] services), or HIV tests for only voluntary counseling and testing (VCT) and PMTCT services; and (c) the program's service capacity according to the volume of services that can be provided, given the existing infrastructure, staff availability and staff skills, and customer access to services.

In the case of HIV tests and laboratory reagents and supplies, the forecast may need to include additional quantities for quality control and training, in addition to client testing. For products that have multiple uses, it may be necessary to forecast demand separately for each use. Examples of forecasting demand separately could include forecasting demand for an antibiotic prescribed for treating sexually transmitted infections (STIs) and opportunistic infections (OIs) under different treatment guidelines, or forecasting usage of an HIV test for diagnostic or confirmatory testing under different testing protocols for PMTCT, clinical diagnosis, or VCT.

ESTIMATING REQUIREMENTS

The term *estimating requirements* consists of determining the quantity of each product needed to meet the forecasted demand and ensuring that the pipeline has adequate stock levels to maintain a continuous supply to service delivery points. The requirements estimate for the forecast period is determined by calculating additional quantities of the product needed to cover any expected product wastage, quality control, lead times, and buffer stocks to the forecasted demand. The requirements estimate is then adjusted by subtracting the quantity of each product already in the system (*stock on hand*) and any quantities already ordered but not yet received (*quantity on order*).

In some cases, the forecasted demand, and consequently the requirements estimate, may need to be reduced to accommodate constraints in the storage and distribution capacity of the logistics system.

ESTIMATING COSTS

The term *estimating costs* involves calculating the cost of procuring all the product requirements. In addition to the commodity cost, other procurement, shipping, handling, customs clearance, storage, and distribution costs may also be included in the total cost estimate.

DETERMINING QUANTITY TO PROCURE

Determining the quantity to procure consists of identifying the quantities of products to be procured. If the cost estimate does not exceed the total funds available, then this step is straightforward and requires little to no adjustment of the estimated requirements. In most cases, the quantity to procure will equal the requirements estimate. If, however, the cost estimate is greater than the available funding envelope, an adjustment must be made to the estimated requirements, either by reducing the number of items to be procured or by recalculating the quantities required of each individual product.

For most public health programs, this step involves prioritizing the items to be purchased according to the conditions to be treated or the people to be served, and then reducing the quantity to procure to fit available funds. In such cases, a variety of methods can be used to arrive at the final quantity of product to be procured, including the use of epidemiological profiles, or ABC and VEN (vital, essential, nonessential) analyses. For HIV/AIDS programs, this step may result in a reduction of the number of people who can be tested for HIV infection or the number of patients who can initiate ART within the period of the forecast.

FORECASTING METHODOLOGIES

In general, the methodology that is selected for forecasting the future demand for services and commodity needs is based on the availability and quality of data on (a) the rate of consumption of drugs or commodities used and (b) the number and type of patients receiving services, as well as on program policies and expansion plans. The following types of data may be used to guide the forecast:

- Demographic data based on characteristics of the target population (e.g., age, sex, geographic location, and urban or rural location)
- Morbidity data on prevalence or incidence of disease or infection in the target population
- Service statistics data on the number of service delivery sites, the volume of services or number of patients per site, and the type of service received
- Logistics data on consumption, losses, and adjustments to inventory, and the stock on hand at the various levels of the in-country supply chain.

For new and expanding programs or services and for existing programs for which those types of data may be unavailable, unreliable, or not predictive of future demand, forecasts may be based on program targets, such as the number of patients expected to access and receive treatment within the period of the forecast. Targets for expanding programs should be based on realistic service delivery and supply chain capacity, as well as on available resources. Although forecasts based on program targets are commonly used to determine commodity needs and cost estimates for procurement, program targets may also be based on the number of patients who could be treated given a specific amount of funding available and the commodity cost per patient.

Forecasts that are based on demographic, morbidity, or target data alone will most often overestimate drug requirements because they do not take into account the actual volume of services being provided or that can be provided, or the quantities of commodities being dispensed or used. Wherever possible, service statistics data on the actual number of patients being treated, as well as logistics data on the actual quantities of drugs dispensed to patients or the actual quantities of commodities used, should be incorporated into the forecast.

THE CONSUMPTION-BASED METHODOLOGY

The *consumption-based methodology* uses logistics data on consumption of commodities in the past as a basis for projecting future needs. Estimates of increases in consumption or other changes in consumption for each product during the period of the forecast are based on past trends in consumption or product usage. Use of the consumption-based methodology requires the availability of data on the quantities of drugs actually dispensed to patients or on the commodities used at service delivery points over a specified period. In many cases, timely and accurate consumption data are not available, and, even if they are available, consumption data alone will not be indicative of future demand in new programs and in expanding programs. Assumptions will need to be made about the rate of program growth, about prescribing and dispensing practices, and about patient needs to complete the quantification.

THE ADJUSTED CONSUMPTION METHODOLOGY

The *adjusted consumption methodology* is an adaptation of the consumption-based methodology that uses the consumption data of one or more facilities that have reliable data and extrapolates from that data to estimate the quantities of commodities needed at other, similar facilities for which no data or unreliable data exist. Again, this methodology requires the availability of timely and accurate consumption data on quantities of drugs dispensed to patients or quantities of commodities used at one or more service delivery sites.

THE MORBIDITY-BASED METHODOLOGY

In the *morbidity-based methodology*, the estimation of commodity needs is based on the application of standard treatment guidelines, testing algorithms, or other treatment protocols to the projected number of patients expected to receive treatment or services within the forecast period. The projected number of patients to be forecasted may be based on demographic data, morbidity data, service statistics data, program targets, or a combination of those data.

Using the morbidity-based methodology for estimating commodity requirements requires that data on the actual number of patients treated or services provided and the estimated number of new patients to be diagnosed and treated or services to be provided within the period of the forecast must be available or must be arrived at through informed assumptions. Standard treatment guidelines, testing algorithms, or other policy guidelines should be clearly documented, disseminated, and assumed to be adhered to by all service providers who have been adequately trained. The accuracy of morbidity-based forecasts depends on the degree to which standard treatment guidelines (STGs) are followed and on the availability of prescribed drugs or commodities when they are needed.

In practice, forecasts may be conducted using two or more types of data and a combination of methodologies. For example, the results of a consumption-based forecast and a morbidity-based forecast may be compared and adjusted to arrive at a best estimate of future commodity requirements.

BACKGROUND

Laboratory services are strategically critical to the success of service delivery in comprehensive public health programs. Specifically, laboratory services have been identified as one of the cornerstones on which those programs are built. As a result, the success of such programs is dictated, at least in part, by quality laboratory services that are able to keep pace with the increasing needs and demands of the programs, including ensuring continuous availability of essential laboratory commodities.

Ensuring continuous availability begins with the strengthening of the laboratory commodity management systems. To this end, quantification of laboratory supplies is a critical first step in ensuring continuous supply. In many settings, however, laboratory services have been incapacitated by years of under funding and neglect. Therefore, given recent and future plans of service expansion, it is even more critical for resource limited countries to make significant investments in strengthening laboratory services, particularly logistics management system including quantification.

ISSUES SPECIFIC TO QUANTIFICATION OF LABORATORY SUPPLIES

LACK OF LOGISTICS DATA

There are unique challenges to quantification of laboratory commodities. Ideally, forecasting should be based on logistics data because past usage data have been found to be the most representative indicator of future usage for forecasting purposes. However, as a direct result of the lack of attention paid to laboratory systems to date, very little data are recorded on usage and on stock levels of laboratory commodities. When data are available, often they are incomplete or unreliable and, therefore, cannot be used for quantification purposes.

In the absence of logistics data, demographic and morbidity data could be used for forecasting purposes. Although this approach is often used when forecasting commodities specific to a particular disease or condition or to a particular program (e.g., Reproductive Health and Family Planning), it is an approach that is extremely challenging to institute for laboratory commodities. Laboratory services are cross-cutting and are, therefore, difficult to tie to a particular condition or program. Even when possible to link a set of laboratory tests to a particular condition or program, it has proven to be impossible to anticipate additional laboratory tests that may be needed for any individual client. For example, although a client who is admitted to the hospital for malaria may routinely receive malaria smear and hemoglobin estimation, it is not possible to predict what other tests may need to be administered as a result of complications that are associated with that specific patient.

Finally, service statistics can also be used for forecasting purposes. Using this methodology, one can use the number of tests conducted during a particular time period to forecast future needs. In DELIVER's experience, most laboratories collect only service statistics, specifically on the number of tests conducted at each facility. Accordingly, the quantification process outlined as follows is based on the use of service statistics for forecasting.

> Note: When more accurate logistics data on laboratory supplies become available, a usage-based (consumption-based) forecasting methodology should be used.

LARGE NUMBER OF COMMODITIES TO BE MANAGED

The second major challenge in the quantification of laboratory supplies is related to the sheer number of commodities that are required. In an effort to simplify the laboratory system and for the purpose of supply chain management, laboratory commodities can roughly be separated into three categories: reagents, consumables, and durables. For quantification, those categories will be refined even further.

Reagents

Reagents are chemicals and biological agents that are used in laboratory testing to detect or measure an analyte, the substance for which you are testing. Reagents vary widely in cost, stability, cold chain requirements, availability, and hazards associated with them.

Consumables

Consumables are items that are used once while performing a test and that are not reused. For quantification, there are multiple categories of consumables. Consumables can include test-specific items such as microscope slides and cover slips. Other consumables cut across all testing services and are classified as general laboratory consumables, such as bleach, alcohol, and gloves.

Durables

Durables are items that can be reused for multiple tests and include glassware that can be washed, sterilized, and reused. For quantification, this category also includes the equipment and instruments used for testing.

STEPS IN QUANTIFICATION

Regardless of the commodity being quantified, there are four main steps to the quantification process: forecasting demand, estimating requirements, estimating cost, and determining the quantity to procure. Product-specific differences will dictate the way each of the four main steps is completed.

PREREQUISITES TO QUANTIFICATION

A number of activities need to be completed before the quantification can be conducted. The information gained when completing those prerequisites will inform and guide the quantification.

DEFINE THE SCOPE AND PURPOSE OF THE QUANTIFICATION

The scope of the quantification will depend on various political, programmatic, financial, and environmental factors. For laboratory supplies, two initial factors that will help define the scope include (a) the laboratory services to be included, and (b) whether or not the quantification is for the whole country or for one sector. National-level quantification is often a useful starting point, but separate quantifications may be needed for different sectors, programs, target populations, geographic regions, funding sources, or supply chains. The number, type, and level of the facilities to be covered by the quantification should also be defined.

Some examples of different scopes for quantifications that have been conducted include the following:

- National-level quantification across all laboratory services to meet the needs of the whole country
- Quantification by health sector (public sector, nongovernmental, or private sector) for the same laboratory services or for different laboratory services
- Quantification by program (e.g., a quantification of laboratory commodities for public sector ART program, STI diagnostic and treatment, TB program diagnostic and treatment, etc.)
- Quantification by target population (e.g., to support pediatric ART patients)
- Quantification by geographic region (e.g., laboratory services for TB may exist in certain regions of the country and not in other regions)
- Quantification by funding source (government or donor organizations that fund procurement of commodities may require separate quantifications).

The purpose of the quantification and how it will address the program's needs must be identified. The following are examples:

- Is the quantification to inform donors about funding requirements and to advocate for resource mobilization for laboratory commodity procurement?
- Is the quantification to estimate national laboratory commodity requirements and to assess the stock status of the pipeline so that supply imbalances can be identified and corrected?
- Is the quantification to support an estimate of commodity procurement, storage, and distribution costs?

The quantification exercise should also answer the following key questions:

- How many tests can be conducted with available funds? Or, conversely, how much would it cost to conduct a target number of tests within a given time period?
- How long will current stocks last given the current usage data and expected rates of growth?
- What quantities of laboratory supplies need to be procured, and when are the quantities needed to avoid stockouts and to support program expansion?

DESCRIBE THE LABORATORY SYSTEM

Before one begins the actual laboratory supplies requirements quantification, it is important to clearly define the programs for which commodities are being quantified. For laboratory systems, given the fact that they support multiple programs, the definition should not only be the program but the services for which the laboratory supplies are required.

From a supply chain management perspective, a program is all the laboratory services that have a common distribution pipeline**.** The laboratory supplies can be provided from the same funding source or from different funding sources, but if they all go into the same distribution pipeline, they are considered supplies for one program and require one quantification.

Conversely, the laboratory supplies can be provided from one funding source or from separate funding sources, but if they are distributed through separate distribution pipelines (e.g., the Ministry of Health (MOH) distribution system and the Mission sector distribution system), each of those pipelines is considered a different program. A separate quantification must be conducted for each program, because supply chain factors such as lead time, buffer stock, and pipeline length may vary by program.

EXAMPLE 1: ONE SUPPLY CHAIN, ONE QUANTIFICATION

In country ***X***'s public sector, laboratory commodities for general health services are funded by the government for all laboratories. The funds for laboratory supplies for blood safety are provided both by the government Global Fund grant and by President's Emergency Plan for HIV/AIDS Relief (PEPFAR). The funds for laboratory commodities to support ART are provided by PEPFAR through the Centers for Disease Control and Prevention (CDC). However, all laboratory supplies are stored and distributed through the public sector, MOH supply chain as part of the national HIV/AIDS program. In this case, you would forecast demand separately for each of the funding sources and then would aggregate the overall quantities required to determine the total quantities of laboratory supplies required by the MOH.

EXAMPLE 2: TWO SUPPLY CHAINS, TWO QUANTIFICATIONS

In country ***Y***, you are asked to conduct quantification for the blood safety, VCT, and sentinel surveillance (SS) activities. As you begin your questioning, you discover that laboratory supplies for VCT and sentinel surveillance programs are procured through the MOH Public Health Unit and MOH Logistics Unit, and are distributed through the MOH regular essential drugs distribution system. The supplies for blood safety are donated by a nongovernmental organization (NGO), briefly stored, and then distributed separately to the government blood collection sites by a private distributor under contract to the NGO. Those programs are two separate programs, and they would require separate quantification exercises. However, within the MOH system, the first step in preparing the overall quantification is that demand for VCT and SS must be forecast separately, before final quantities required can be aggregated.

STANDARDIZE LABORATORY POLICIES AND PROCEDURES

Before one conducts the standardization process, it is essential to obtain the following relevant laboratory policies and procedures, if possible:

- National laboratory policies
- National laboratory guidelines (including test menu and technique by level)
- Laboratory standard operating procedures (SOPs) by level, including quality control procedures.

Quantification for laboratory supplies depends on test menus and test techniques used in the laboratory system. If national policies and procedures have been developed, they need to be reviewed and their use verified with key stakeholders to confirm that test menus and techniques identified in the policies and procedures are current and are practiced. If national policies and procedures have not been developed, a recommendation should be made that they be developed. As laboratory technologies rapidly evolve, guidelines need to be kept current with the most appropriate and accurate tests and techniques, which will help maintain a quality laboratory program. The development of national policies and procedures will facilitate the coordination of laboratory efforts at a national level, which reduces inefficiencies and wastage of resources in the laboratory system.

In the absence of having detailed SOPs, key stakeholders should embark on the process of standardizing laboratory procedures. Standardization as a process includes defining the following elements of the laboratory system:

- Test menus by level
- Test techniques by level
- SOPs by test and by level
- Instrumentation by level.

Each of the above elements should be defined and implemented across all laboratories at all levels of the system.

Because of the lack of logistics data for use in quantification, the standardization process becomes even more critical. When using service statistics data for the quantification of laboratory commodities, the volume of each test type and technique at each level of the system drives the forecast. In a nonstandard system, the test types and techniques can reach into the hundreds, with subsequent commodity needs reaching into the thousands. This number presents an insurmountable obstacle to the quantification of these commodities. The process of standardization provides a critical focus for the system and reduces the number of laboratory commodities needed to a manageable number.

For example, for a single hemoglobin test, approximately eight different manual techniques could be used to conduct the test. The different commodities required for each technique are listed in table 1. If the quantification were to include all eight manual testing techniques, 9 reagents, 14 consumables, and 22 durables or pieces of equipment would be needed.[1] Therefore, a total of 45 commodities would be required for use in one test, at one level of the system. If each laboratory at that level conducts 50 different tests using a variety of testing techniques, the commodity needs can easily expand to thousands of different commodities. Those needs can then be multiplied by the number of levels in the laboratory system, which results in a significant managerial and financial burden on the laboratory program.

1. Note that those test techniques are exemplary and additional commodities may be required for slightly different operating procedures. In addition, automated hemoglobin estimation techniques presented in this guide were not analyzed.

TABLE 1. MANUAL HEMOGLOBIN TESTS AND LABORATORY SUPPLIES NEEDED

Test Technique	Reagents	Consumables	Durables/Equipment
Filter Paper Comparison		• Filter/blotting paper • Sterile lancet • 70% alcohol • Cotton wool	• Color comparison chart
Copper Sulfate Method	• Copper sulfate	• Graduated transfer pipette • Capillary tube • Sterile lancet • 70% alcohol • Cotton wool	• Flasks • Weighing scale • Amber tinted bottles
Hematocrit by Centrifuge		• Capillary tube • Sterile lancet • 70% alcohol • Cotton wool	• Microhematocrit centrifuge
Lovibond Comparator	• Ammonia OR • Potassium ferricyanide • Potassium cyanide • Potassium dihydrogen phosphate • Surfactant	• Blood pipette • Sterile lancet • 70% alcohol • Cotton wool • Parafilm or foil	• Glass tubes • Lovibond comparator • Colored glass standards
Grey Wedge (BMS) Photometer	• Saponin powder • EDTA powder	• Toothpicks • Sterile lancet • 70% alcohol • Cotton wool	• BMS grey wedge photometer • Glass chamber for blood sample • Calibrating glass standard • Batteries (1.5 volt)
Sahli Method	• Hydrochloric acid	• Sterile lancet • 70% alcohol • cotton wool	• Sahli hemoglobinometer • Sahli blood pipette • Dropper
HemoCue		• Cuvettes • Standard cuvettes • Sterile lancet • 70% alcohol • Cotton wool	• HemoCue instrument • Batteries
Colorimetry-Hemiglobincyanide Method	• Potassium cyanide • Potassium dihydrogen phosphate • Surfactant	• Standard solution of hemoglobin • Graph paper • Tube labels	• Photoelectric colorimeter • Cuvettes • Test tubes • Watch or timer • Calibrated pipettes
TOTAL NUMBER:	**9**	**14**	**22**

The standardization of the laboratory system should take place through a consensus-building workshop that includes representatives from all levels in the health system that are providing laboratory services, the National Public Health Laboratory Services or an equivalent institution, and key stakeholders involved in laboratory services.

The standardization process provides many benefits. It not only simplifies the quantification process but also contributes to quality testing throughout the system. The benefits of standardization include the following:

- High-quality, reliable, and consistent test results at all facilities
- Reduction in number of laboratory commodities
- Manageable supply chain for laboratory commodities.

Note: An example of a standard test menu by level can be found in annex A

However, the standardization process is not without challenges. The following are some of the primary challenges:

- The tests and techniques agreed on in the standardized system may not be consistent with the tests and techniques that laboratory staffs have been previously trained on or that they are currently using in their laboratories. For example, the standardized system may call for a hemoglobin test to be conducted using the copper sulfate method at one level of the system. However, laboratory staff at that level might not have received any previous on-the-job training or academic training on the copper sulfate method. As a result, a large-scale training effort may be required to both inform laboratory staff about the new standardized system and to train them on the specific tests and techniques that the new system requires.
- The standardization process will almost certainly result in the obsolescence of equipment that had been in use in the nonstandard system. At each level, facilities will face the challenge of determining what to do with that equipment and of developing strategies to ensure that it will not be used under the standardized system.
- In many of those laboratories, the technique used for testing and, consequently, the procedures followed have been determined by the availability of supplies. In a standardized system, the testing technique should be determined by the agreed-on test menu, technique, and instrumentation. Over time, this challenge should become less of an issue as the new tests and techniques and the associated commodities are phased into the laboratory system, and as the previously used commodities no longer required in the new system are phased out.

DETERMINE THE PERIOD OF THE FORECAST

Medium-term forecasts of laboratory commodity requirements for two to five years are recommended to assist in program planning and in mobilizing financial resources for procurement of laboratory supplies to support program expansion. The quantification and the costing of commodity requirements for procurement with available funds for a one-year period are recommended for short-term procurement planning and should include specific quantities of each product to be procured and a shipment delivery schedule for the year. Because of the rapidly changing environment inherent to laboratory systems, procurement plans for one year at a time are recommended, and such plans should be revised and updated every six months to reflect actual services provided and immediate plans for scale up of services.

DETERMINE THE TARGET NUMBER OF TESTS TO BE CONDUCTED FOR EACH FORECAST YEAR

Although targets based on population and disease prevalence data alone may be useful for advocacy or resource mobilization, they should not be used for procurement planning. Those targets tend to highly overestimate commodity requirements because they are not based (a) on any actual services provided or commodities used, (b) on an assessment of realistic service delivery capacity or supply chain capacity, or (c) on resources available to support program growth.

Nationally accepted program targets that are based on population and disease prevalence data should be reviewed and modified on the basis of previous assessments, evidence, or considerations of national- and facility-level “readiness” or capacity to provide laboratory services and manage the laboratory system supply chain. Realistic target test numbers should be based on the following:

- Current level of service provision (number of sites with trained and sufficient providers, and infrastructure) and plans for expansion
- Current status of laboratory commodity supply and product availability at laboratories (stock status assessment at the facility and at the national level)
- Plans for financing and procuring laboratory supplies (sources and amounts of funding available for procurement, disbursement schedules, procurement mechanisms, and respective lead times).

COLLECT THE REQUIRED DATA

The final prerequisite to undertaking a quantification exercise is to collect the data that will be required before and throughout the quantification process. Collecting the data required to complete the quantification will probably be the most time-consuming and difficult of all the steps in the quantification process.

The minimum items that should be collected for use in the quantification process include the following:

- Average test numbers for each test technique by level
- Current inventory of equipment at each facility (necessary only if quantification includes procurement of equipment)
- Current stock status of all laboratory commodities throughout the system
- Expected shipments of laboratory commodities
- Rates of loss and wastage.

In cases where key data are not available or are of very poor quality, it may be necessary to make estimates based on information gathered from key informants.

The following steps may be useful as a guide:

- Identify the type of program (e.g., MOH, NGO, faith-based, pilot or research).
- List all laboratory services provided (ART, TB, malaria, etc.) or those relevant for the quantification.
- Describe the model of services (the level and type of facilities where laboratory services are provided such as a primary, secondary, tertiary, community-based, or outreach facility).
- Ascertain national guidelines for all laboratory testing services identified, including recommended or required testing protocols. (As part of the data collection process, one should verify the product registration and import requirements for those commodities.)
- Identify suppliers for each laboratory commodity.

For laboratory commodity financing and pricing information, the following steps are necessary:

- Identify all sources of financing for laboratory supplies (the government, international donor agencies, foundations, and private sector donation programs).

- Determine the amount and duration of each financial commitment for laboratory commodity procurement. Identify specifically when funds will be available for use.
- Identify the procurement mechanisms and suppliers for each product (national bulk procurement, procurement through local distributors, or direct donation of product).
- Verify local and international pricing information for each type of laboratory commodity.
- Identify any cost-recovery or cost-sharing mechanisms in effect. Are there any costs associated with laboratory services (co-pay, free, sliding fee, partial subsidy)? What are the likely implications of the costs on client uptake of testing services?
- Identify any restrictions on financing regarding the types of laboratory supplies that can be procured (for example, funds from the Global Fund to Fight AIDS, Tuberculosis, and Malaria can be used only to procure laboratory supplies from World Health Organization's prequalified suppliers, on the other hand PEPFAR funds might allow only for laboratory supplies to be procured from an approved FDA list or an approved CDC list).
- Verify flexibility in amounts and availability of funding (for example, are there potential funds that can be reallocated for procurement of laboratory supplies, and how long would reallocation take?).

For logistics data and supply chain information (when using logistics data), here are the steps:

- Obtain national- and facility-level logistics data on usage of laboratory commodities, losses and adjustments, and stock on hand, if available.
- Calculate the wastage rate of laboratory supplies due to expiration, loss, or damage of the products that occur during storage, distribution and usage. Without data, this wastage rate is currently assumed to be 3 –10 percent until data from stock cards become available.
- Determine whether an inventory control system is in place for management of laboratory supplies.
- Determine procurement lead times, supplier schedules, and lead times for delivery of supplies.
- Determine established buffer stock levels or maximum and minimum inventory levels, if available.
- Confirm facility order intervals.
- Determine the frequency and the timing of procurement procedures.

Sources of Data

The likely sources for much of the data needed for laboratory commodity requirements quantification are key informants and program documents in-country.

Key informants to interview include managers from national public health laboratory services; laboratory scientists representing all levels of the health system from both the public and the private, not-for-profit sectors; and all stakeholders (NGOs, donors, etc.) supporting laboratory services.

Program documents that are likely to provide useful information include national laboratory policy and guidelines, reports of previous quantifications and procurements. The other sources of information can be the HMIS and LMIS, when available.

When forecasting demand for any of the commodity types, there are constraints in the type and quality of data available. Therefore, multiple assumptions will be required about specific tests and techniques by level, by capacity and quality of service delivery, by procurement and supplier lead times, and by status of the in-country supply pipeline. A consultative process with laboratory stakeholders will enhance accuracy and will ensure that the final quantities to order have been developed with input from a range of laboratory services providers. It is important to document the sources of information and input from key informants that are used to explain the assumptions for the quantification. The quantification should be reviewed and updated at least every six months and when any of the major assumptions change.

Examples of assumptions may include the following:

- The appropriate application of testing protocols
- The number of tests per level
- The forecasted demand for general consumables (commodities used across all procedures in the laboratory and sometimes outside the laboratory within the facility)
- The capacity of the supply chain to manage laboratory supplies
- The capacity of human resources
- The rate of wastage.

Useful Outputs

Extremely useful, visual outputs that can be developed during or after the data collection process are laboratory commodity flow maps for each program or laboratory services that show the suppliers (funding sources) of the commodities, the commodities supplied by service, and the general distribution flow of the laboratory commodities from suppliers to points of use. Documenting the results of the data collection (and defining the program) will avoid double-counting of some laboratory commodity requirements and the failure to count other commodity requirements.

FORECAST DEMAND FOR LABORATORY PRODUCTS

The first step in the quantification process is to estimate the quantity required for each laboratory commodity to meet customer demand for the forecast period on the basis of service capacity and other programmatic factors that have already been taken into account through the definition of the scope of the quantification.

When quantifying for laboratory commodities, the forecasted demand is broken down into three distinct parts: (a) forecasted demand for reagents and consumables that are used per test, (b) forecasted demand for general consumables, and (c) forecasted demand for durables. Calculating forecasted demand for each of those categories of products requires a slightly different approach and different data. The following sections in the guide describe the steps that should be taken for each level of the system by category of product.

FORECASTING DEMAND FOR REAGENTS AND CONSUMABLES USED BY TYPE OF TEST

Assuming that the technique for each type of test has been defined in the standardization process, forecasting demand for reagents and consumables used by type of test requires the following steps:

DETERMINATION OF THE SPECIFIC COMMODITIES NEEDED

To forecast the demand for reagents and consumables used per test, one needs to determine the commodities used for each test, their basic units, the specifications, and the quantities needed to conduct that specific test. One or more products are often needed to conduct a single laboratory test, and each testing technique often uses different commodities. Therefore, there should be consensus on which commodities are needed, to avoid further complicating an already complex system.

Once each commodity has been identified, its basic unit needs to be determined and specified[2] in consultation with laboratory services managers and scientists. Similarly, each test technique uses a specific quantity of a product to conduct the test. Therefore, the quantity of each commodity needed per test should also be determined. The amount of each commodity needed per test can be found in the SOPs, when available. If not available, international references, such as *Laboratory Practice in Tropical Countries* (Cheesbrough 2000), should be sought to facilitate this process.

For example, to conduct a test for bacterial infections, one can use a gram stain blood smear technique. Table 2 identifies the commodities, including their basic unit, specifications, and quantity, which are needed for this particular test.

2. Specifications provide the details that a procurement agent requires to procure the exact product needed for the test requirements.

TABLE 2. COMMODITIES NEEDED PER TEST

Commodity	Basic Unit	Specifications	Quantity Needed Per Test
Crystal Violet Stain	1 g	Stain powder, GPR	0.025 g
Potassium Iodide	1 g	Powder, general purpose reagent (GPR)	0.02 g
Iodine	1 g	Crystals, GPR	0.01 g
Acetone	1 L	Analytical reagent	0.0004 g
Neutral Red	1 g	Stain powder, GPR	0.0005 g
Microscope Slides	1 slide	Single frosted, pre-cleaned, glass, 76.2 mm x 25.4 mm x 1.2 mm	1 slide

Determining the quantity of each commodity needed per test is further complicated by the nature of some of the laboratory supplies being used. The nature of such products, which will be used to conduct different tests, should be taken into account when determining the quantities needed per test. For instance, many laboratory reagents require reconstitution, which makes it difficult to determine the quantity needed per test.

In the preceding example, crystal violet stain is supplied in a powder form. If one is to use this particular stain, it must be reconstituted into a liquid form, which changes the basic unit from grams to milliliters (mL). SOPs will likely require a quantity of liquid (mL) for each test. If one is to determine the g quantity of crystal violet stain powder per test, the mL quantity will have to be converted to grams as follows:

- First, 1 g is used per 50 mL of distilled water.
- Then, 50 mL of solution is used for 40 tests.
- Therefore, 1 g of powder is used for 40 tests.
- Thus, 1 test uses 1 g/40 tests = 0.025 g/test.

Note: It is vital that formulas such as those should be noted in the quantification assumptions to show how the quantity of reagents needed for each test was determined.

It should be noted that any commodity used for quality assurance and quality control purposes should be included in the forecasted demand.

MULTIPLICATION OF THE COMMODITIES NEEDED PER TEST BY THE AVERAGE TESTS DONE

For each test, the average number of tests performed per month at the particular level should be determined. This number will be multiplied by the quantity of each commodity needed to conduct one test. The results will finally be converted into yearly requirements and will give the commodities needed per facility on an annual basis for the specific test.

For example, if facilities at a particular level of the system conduct an average of 123 tests per month for bacterial infections using a gram stain blood smear technique, the annual commodity requirements would be adjusted as follows in table 3.

TABLE 3. ANNUAL COMMODITY REQUIREMENTS PER FACILITY

Commodity	Basic Unit	Average Monthly Tests Per Facility	Quantity Needed Per Test	Quantity Needed Per Month	Quantity Needed Per Year
Crystal Violet Stain	1 g	123	0.025 g	3.075 g	36.9 g
Potassium Iodide	1 g	123	0.02 g	2.46 g	29.52 g
Iodine	1 g	123	0.01 g	1.23 g	14.76 g
Acetone	1 L	123	0.0004 g	0.0492 g	0.5904 g
Neutral Red	1 g	123	0.0005 g	0.0615 g	0.738 g
Microscope Slides	1 slide	123	1 slide	123 slides	1,476 slides

SUM COMMODITY REQUIREMENTS FOR ONE FACILITY

Up to this point, commodity needs have been expressed in terms of each particular test and technique. However, many laboratory commodities not only are used in one type of test but also are used to conduct different types of tests. For this reason, it is important to sum requirements for each commodity across all the different types of tests conducted.

For example, crystal violet stain is used when testing for bacterial infections using the gram stain blood smear technique. It is also used when conducting a high vaginal swab (HVS) test using a microscopy technique. Assuming that those tests are the only tests and techniques that use crystal violet stain, the commodity requirements for each of the tests should be added together. Therefore, if 36.9 g of crystal violet stain are needed annually for gram stain blood smear tests and if 26.7 g of crystal violet stain are needed for HVS microscopy tests, a total of 63.6g of crystal violet stain are needed at the facility annually.

ROUND-UP OF COMMODITIES NEEDED FOR ONE FACILITY TO THE APPROPRIATE PACKAGING SIZE

Once total commodity needs for one facility have been determined, they should be rounded upward to reflect the packaging size available for that specific commodity. For example, if facilities at a particular level of the system require 63.6 g of crystal violet stain annually, when considering the packaging size of each of the commodities required, the annual commodity requirements would be adjusted as follows in table 4.

TABLE 4. ADJUSTED ANNUAL COMMODITY REQUIREMENTS PER FACILITY

Commodity	Basic Unit	Quantity Needed Per Year	Packaging Size	Adjusted Quantity Needed Per Year	Packages Needed Per Year
Crystal Violet Stain	1 g	63.6 g	25 g	75 g	3 packages

The same process should be undertaken for each commodity that is used at the facility.

Note: While it may seem logical to divide the total units required at a particular level by the packaging size, to calculate the total number of packages required, it is important to remember that packages cannot typically be split or shared among different facilities.

To determine the yearly requirement for each product, for all laboratories, you must first round up to the packaging size or you will underestimate the total number of packages required. An inaccurate count would make the distribution of that product to the laboratories very challenging because the product is procured and distributed in packages and not in bulk. The only exception is when there is in-country capacity for repackaging products, which requires additional resources.

In the example that follows, this particular level has five laboratories, and each laboratory requires 63.6 g of crystal violet stain annually, which is procured in bottles of 25 g. In table 5, the facility rounds up to the packaging size.

TABLE 5. ROUND-UP OF YEARLY REQUIREMENT TO PACKAGING SIZE BY FACILITY

Commodity	Annual Quantity Needed Per Facility	Packaging Size	Adjusted Annual Quantity Needed Per Facility	Annual Packages Needed Per Facility	Number of Facility at This Level	Annual Packages Needed Per Level
Crystal Violet Stain	63.6 g	25 g	75 g	3	5	15

In table 6, rounding up to packaging size is done after the total quantity needed for the level is calculated.

TABLE 6. ROUND-UP OF YEARLY REQUIREMENT TO PACKAGING SIZE BY LEVEL

Commodity	Annual Quantity Needed Per Facility	Number of Facilities at This Level	Total Quantity Needed Per Level	Packaging Size	Annual Packages Needed Per Level
Crystal Violet Stain	63.6 g	5	318 g	25 g	12.72

The preceding example demonstrates that about 13 bottles of 25 g of crystal violet stain would be required for all five laboratories—if rounding up to packaging size is done by level and not by facility. Equitably dividing 13 bottles among five labs would be very challenging and would mean opening and sharing 3 bottles among the five laboratories.

MULTIPLICATION OF FINAL COMMODITY REQUIREMENTS FOR ONE FACILITY BY THE TOTAL NUMBER OF FACILITIES

After annual commodity needs have been adjusted according to packaging size, the commodity requirements per level of the laboratory system need to be calculated. In the previous step, adjusted quantities needed per year were calculated for one facility. To determine the annual quantities needed for a particular level, those adjusted needs per facility are multiplied by the number of facilities in that level of the laboratory system.

If one uses data from the previous example, if there are 50 facilities in the particular level of the laboratory system, the quantity of crystal violet stain needed for that level would be the adjusted quantity needed per year for one facility, 75 g or 3 packages, multiplied by 50 facilities. This process results in a total of 3,750 g or 150 packages of crystal violet stain needed annually for that level.

SUM COMMODITY REQUIREMENTS ACROSS THE LABORATORY SYSTEM

After commodity needs have been summed across all tests at each level, the final step in the process is to sum the commodity requirements across the laboratory system. This step will result in the total commodity requirements across all levels of the laboratory system. Those quantities will be referred to as the forecasted demand for reagents and consumables used per test.

FORECASTING DEMAND FOR GENERAL LABORATORY CONSUMABLES

Although quantifiable per test, general laboratory consumables are commodities used across many tests, and those items can even be found outside the laboratory (e.g., alcohol, gloves, disinfectant, etc.). Without question, the commodities are necessary to run a laboratory and must also be included in the forecast. Ideally historical usage data would guide forecasting demand of general consumables. However, in the absence of logistics data, it may be necessary to make assumptions on the usage of those commodities, in consultation with laboratory personnel. It is critical to document the assumptions, as well as all assumptions made throughout the quantification process. (Refer to annex B.)

Unlike the quantification of the supplies discussed so far, the steps of determining quantities required by type of test and technique are not applicable to general laboratory consumables. Hence, the first step in forecasting demand for general consumables is identifying each consumable, its basic unit, and the specifications. Next, the quantities required for one facility will be determined. Those quantities should then be rounded up to reflect the packaging size available for each commodity. As previously mentioned, this step should take place before multiplying the commodity requirement for one facility by the total number of facilities at that level. The final step is to sum the commodity requirements at all levels of the laboratory system. Those quantities will be referred to as the forecasted demand for general laboratory consumables.

FORECASTING DEMAND FOR DURABLES

For quantification, durables are divided into two categories: supplies and equipment, as shown in table 7.

TABLE 7. DURABLE SUPPLIES AND EQUIPMENT

Durables	
Supplies	**Equipment**
Anaerobic Jar	Hematology auto-analyzer
Bijou Bottle	Binocular-powered microscope
Serological Pipette	Enzyme linked immunosorbent assay (ELISA) reader and washer

Forecasting demand for durables will require the same steps as for estimating the quantity required for general consumables. However, equipment is usually not included in the forecast unless specifically requested. On the one hand, if it is included, the step of rounding up quantities required for one facility to the appropriate packaging size is not applicable. On the other hand, the forecast should always include spare parts that are likely to be needed during the forecast period, depending on a number of factors, including the following:

- Inclusion of spare parts in the equipment contract
- Availability of spare parts in the local market
- Availability of funds to procure spare parts.

ESTIMATE REQUIREMENTS

The second major step in the quantification process is to adjust forecasted demand to account for product wastage, lead time stock, buffer stock, stock on hand, and quantity on order. At this step in the quantification, an assessment of the in-country supply status is needed to calculate requirement estimates of each commodity expected to be stored, distributed, and used in the laboratory system. The requirement estimates should include the quantities of laboratory commodities required to meet forecasted demand and to fill the pipeline with adequate stock levels.

To estimate requirements for the next one-year procurement period, adjustments will need to be made to the forecasted demand to account for product wastage, lead time, buffer stock, stock on hand, and quantity on order. (Note: The adjusted quantity to order may be greater or less than the quantity forecasted, depending on current stock on hand and expected usage rates.) The quantity to order may also need to be further adjusted to reflect current storage and distribution capacity, especially for products that may require refrigeration.

ADJUSTMENT OF TOTAL FORECASTED DEMAND FOR PRODUCT WASTAGE, LEAD TIME, AND BUFFER STOCK

Using Excel spreadsheets or other software designed to calculate the quantity to order of each laboratory commodity, the total quantity of each laboratory commodity required at all levels of the system for the forecast period is entered as the base number from which all adjustments will be made.

PRODUCT WASTAGE

It is important to account for product wastage, including product loss through spillage, through incorrect measurement or through damage during use. Initially, product wastage rates can be assumed to be 10 percent of the total quantity required. However, product wastage rates can drop with improved testing skills, appropriate equipment, and infrastructure to around 3 percent of the total quantity required.

LEAD TIME STOCK AND BUFFER STOCK

The estimated requirements needed to fulfill demand during the forecast period also need to be adjusted to include lead time and buffer stock levels throughout the system during the forecast period. Lead time stock is the laboratory commodity stock kept on hand and used between the times the new stock is ordered and the new stock is received and available for use. Buffer stock required is the laboratory commodity stock kept on hand to protect against stockouts caused by delayed deliveries, markedly increased demand, or other unexpected events.

Buffer stock is measured in months of stock and is required for the calculated annual commodity requirements. It is, therefore, calculated by dividing the annual requirement by 12 to determine monthly requirements, which will then be multiplied by the number of months of buffer stock required to cover for uncertainties, such as a sudden increase of usage or delays in delivery of supplies.

Determining the lead time stock required is done in much the same way that determining the buffer stock requirement is done. For each laboratory commodity, multiply the previously calculated average monthly requirement by the number of months of lead time stock required to cover stock used between the time new stock

Note: It is very important to involve the in-country counterparts when setting the buffer stock and lead time stock levels.

is ordered and the time that new stock is received and available for use. This formula will result in the total lead time stock required. Initially, lead time levels may also include the time required for preparation of the quantification, for allocation and disbursement of funds, for contracting of suppliers, for procurement, for shipment delivery, for customs clearance, for inspection, and for receipt of products into the central warehouse.

Lead time stock and buffer stock requirements are then added to the total forecasted demand that has been adjusted for product wastage.

Adjusted Requirements Estimate	=	Total Forecasted Demand	+	Estimated Requirements for Product Wastage	+	Estimated Requirements for Lead Time and Buffer Stock

FURTHER ADJUSTMENT OF THE REQUIREMENTS ESTIMATE TO ACCOUNT FOR EXPECTED STOCK ON HAND AT THE BEGINNING OF THE PERIOD

The adjusted requirements will need further adjustment to account for the estimated stock on hand (SOH) at the beginning of the forecast period. The estimated stock on hand is calculated using the following formula:

Estimated SOH at beginning of forecast period	=	Current SOH	+	Quantity on Order	–	Estimated Usage	+/–	Estimated future Losses and Adjustments

It is important to remember that the current SOH includes the stock balances in each of the laboratories included in the quantification, as well as any stock stored at central or intermediate level storage.

For more details on this calculation, see the *Contraceptive Forecasting Handbook for Family Planning and HIV/AIDS Prevention Programs* (DELIVER 2000).

To arrive at the actual quantity to order, subtract the estimated SOH at the beginning of the forecast period from the adjusted requirements estimate. The resulting annual quantity to order is the quantity of each laboratory commodity needed to ensure full supply at laboratories for the forecast period.

Note: If a logistics system has not been designed, logistics data on SOH and usage of laboratory supplies will not be available at the time the quantification is conducted. Assumptions about national stock and facility stock levels, lead times for funding disbursement and procurement actions, recommended buffer stocks, and supplier delivery schedules and lead times may need to be made.

Quantity To Order	=	Adjusted Estimated Requirements	–	Estimated SOH at Beginning of Forecast

Note: Additional adjustments in the quantity to order may be required at this point in the quantification to reflect the volume of product that can be adequately stored and distributed to ensure the quality and security of the laboratory commodities. Using sources of information on packaging and shipment sizes, the packaging dimensions of laboratory commodities may be used to calculate the volume of incoming shipments and may be compared to actual storage space available in-country. The estimates of shipment volume and storage capacity are particularly important for reagents that may require refrigeration.

ESTIMATE COST REQUIREMENTS

At this stage in the quantification process, the total cost estimate of the requirements is calculated. Those results can then be used for program planning and for resource mobilization.

Updated sources of information on reagents and laboratory consumable prices, supplier rates, preferential pricing, and eligibility for donation programs will be needed to estimate the cost of the quantities of each laboratory commodity to be ordered. In addition, information on the cost of insurance and freight, customs clearance and duties, and in-country storage and distribution costs may need to be added to the cost of the quantities of laboratory supplies to be procured (if not included in supplier rates, budgeted for through other mechanisms, or waived).

Using Excel spreadsheets or other software, enter the quantity to order as the total number of packing units to be ordered for the forecast period.

Using the cost per pack as the unit of measure for calculating the total cost estimate, multiply the quantity to order of each commodity by the cost per pack to arrive at the total cost per commodity for the forecast.

$$\begin{array}{c} \text{Total Cost} \\ \text{Per Commodity} \end{array} = \begin{array}{c} \text{Quantity} \\ \text{to Order} \end{array} \times \begin{array}{c} \text{Cost} \\ \text{Per Pack} \end{array}$$

Depending on the purpose of the quantification and on the available sources of funding for procurement of laboratory supplies, additional cost comparisons between suppliers may be required. Using the same approach, one may need to apply different supplier rates and costs per pack to arrive at alternate total cost scenarios that should be considered when making decisions on funding sources and allocations for procurement.

RECONCILING COST OF REQUIREMENTS WITH AVAILABLE FUNDING AND ADJUSTING QUANTITY TO PROCURE, IF NEEDED

The final step in the quantification process is to compare available funding to the cost estimate and to adjust the quantity to procure, if needed. Those results can then be used for short-term procurement planning.

The final decision on the quantities to procure will be determined by the amount of funding available for procurement of laboratory supplies. Where sufficient funding is available, the final quantities to procure each laboratory commodity will be the same as the quantity to order resulting from the quantification.

In the current environment of increasing financial resources for laboratory supply procurement, funding may be adequate to ensure full supply for targeted tests for the period of the forecast where service delivery and supply chain capacity exist. In other situations, the purpose of the quantification may be to determine how many laboratory tests can be provided in a year given a specific amount of funding available. A map of funding commitments can be used to compare forecasted demand with available funding.

DELIVER recommends flexible regular shipments in which shipment quantities can be adjusted to respond to uptake in testing services, changes in testing demand, and rates of consumption of laboratory supplies. Agreements with suppliers may also need to have the flexibility to delay shipments of annual quantities procured if uptake of services does not meet expected demand.

SUMMARY OF CHALLENGES AND LESSONS LEARNED IN QUANTIFICATION OF LABORATORY COMMODITIES

In DELIVER's experience with preparing quantifications of national-level laboratory supplies, a number of challenges were identified. Those challenges have been summarized and were used to inform the approach to quantification presented in this guide. They include the following:

CHALLENGES

- Data on usage of laboratory supplies are limited and, when available, are often unreliable or insufficient for use in quantifying requirements for laboratory supplies.
- Standard operating procedures for testing services are often lacking. Laboratories tend to individually develop their own SOPs, which are based on the experience of personnel and which result in inconsistent techniques and procedures across laboratories at the same level.
- Techniques that are used for testing and procedures followed have been dictated by availability of supplies rather than by standard protocols.
- Implementation of a standard system can pose challenges in training all laboratory personnel in the recommended testing techniques. Furthermore, the question of functional machines not used in the application of the recommended SOPs is a pending issue in many cases.
- Program targets may not take into account the testing capacity to provide services and supply chain capacity to finance, procure, and manage greater volumes of laboratory supplies.
- Multiple sources of funding, procurement mechanisms, and distribution channels are used for laboratory supplies.
- Quantification capacity at the country level and at the program level is limited.
- Communication and coordination between policymakers, service providers, funding sources, and procurement agents on issues related to the selection, quantification, and procurement of laboratory supplies are lacking. As a result, incompatibility of reagents and equipments procured from different sources is a frequent issue.

Quantification and procurement occur when funding becomes available, when identifying commodity needs, and when mobilizing resources for procurement rather than as a program planning activity. This lack of planning has led to stockouts and to expensive emergency procurements.

LESSONS LEARNED

The following lessons were also identified and documented, and have been incorporated into the approach to quantification presented in this guide. The lessons include the following:

- The quantification exercise itself is time intensive and resource intensive. Therefore, adequate time and resources to conduct the quantification exercise should be planned for and budgeted for.
- Quantifications are currently based on informed assumptions but they will become more evidence based over time as the availability and quality of data improves. Therefore, simultaneous efforts to strengthen the LMIS are encouraged.
- In the absence of logistics data, the most appropriate methodology for quantifying laboratory supplies seems to be service statistics using the number of each test performed over a period of time, except for general laboratory consumables and durables. These commodities require developing assumptions on usage data, in consultation with laboratory personnel.
- Quantification requires a consultative process with multiple stakeholders to inform the assumptions about the selection, quantification, and procurement of laboratory supplies.
- Before quantifying laboratory supplies, one should conduct a standardization exercise to either develop or update tests menus, techniques, testing procedures, and equipment for each level of the health system.

- The standardization process should always be a consultative workshop, with representatives from all programs and with levels providing testing services, donors, and all key players in laboratory services. It is a critical step toward transferring ownership of the results to in-country stakeholders. The meetings can also help with mobilizing resources, setting expectations, and promoting collaboration and coordination, especially if delays in commodity availability occur.
- The quantification should be based on realistic program plans and on available financing.
- The results of the quantification should be used to determine specific order quantities and shipment schedules for short-term procurement planning on the basis of available funding.
- The results of the quantification should also be used for medium- and long-term program planning and resource mobilization for laboratory testing services.
- The quantification should be reviewed and updated at least every six months, and procurement plans should be adjusted accordingly.

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APPENDIX A
TEST MENU AND TECHNIQUE BY LEVEL

Tests Performed at Health Center Laboratory	
Laboratory Test	**Standard Technique**
❒ Hemoglobin estimation	❒ Oxyhemoglobin, Lovibond comparator ❒ Cyanmethemoglobin, Sahli
❒ Blood slide for haemoparasites	❒ Field stain
❒ Stool microscopy for parasites	❒ Direct saline, iodine
❒ Sputum for AFB	❒ ZN stain
❒ Skin slit for AFB	❒ ZN stain
❒ Urine sediment microscopy	❒ Direct microscopy
❒ Urine protein, sugar	❒ Uristix
❒ Syphilis screening	❒ Rapid plasma reagent (RPR)/VDRL carbon antigen
❒ Sickle cell screen	❒ Sodium metabisulphite
❒ Genito-urinary tract specimens	❒ Wet prep/Gram stain/KOH
❒ Pus swabs	❒ Gram stain
❒ Bubo aspirate (plague)	❒ Wayson staining
❒ HIV screening	❒ Rapid screening kits
❒ Blood grouping	❒ Tube method
❒ Rhesus typing	❒ Tube
❒ Total white cell count	❒ Manual, Hemocytometer using Turks fluid
❒ Differential white cell count	❒ Manual, using stained thin film
❒ Cerebrospinal fluid microscopy	❒ Gram/Leishman/Turks fluid
❒ Cerebrospinal fluid chemistry	❒ Turbidimetric
Additional Tests Performed at District Hospital Laboratory	
❒ Concentration technique ❒ Blood ❒ Stool	 ❒ Buffy coat (Knotts) ❒ Formal ether
❒ Urine qualitative chemistry (protein, sugar, ketones, blood bilirubin, urobilinogen)	❒ Uristix
❒ Skin snip for microfilaria	❒ Saline direct
❒ Collection and fixation of cytological smears	❒ Formalin
❒ Collection and fixation of histological specimens	❒ Formalin

Tests Performed at the Regional Hospital Laboratory	
Laboratory Test	**Standard Technique**
❒ Hemoglobin estimation ❒ Total white cell count ❒ Differential blood counts	❒ Hematology analyzer
❒ Platelet count ❒ Reticulocyte count ❒ Blood indices	❒ Hematology analyzer
❒ CD4/CD8 count	❒ Flow cytometer ❒ Non-cytofluorometric ❒ Manual
❒ Viral load	❒ HIV RNA ❒ Real Time PCR ❒ Heat Dissociated p24 antigen ❒ Cavidi RT
❒ Sickle cell screening test	❒ Sodium metabisulphite
❒ Blood slide examination for parasites	❒ Manual microscopy (field) ❒ Concentration
❒ Film comment	❒ Manual microscopy- Romanosky
❒ Stool microscopy	❒ Direct saline/iodine concentration
❒ HIV screening	❒ Rapid screening kits
❒ Hb types	❒ Electrophoresis
❒ Serum proteins	❒ Electrophoresis
❒ Hepatitis B screening	❒ Rapid ELISA
❒ Syphilis screening	❒ RPR/VDRL carbon antigen
❒ Serum bilirubin ❒ SGOT (serum) ❒ SGPT (serum) ❒ Alkaline phosphatase (serum) ❒ Renal function tests ❒ Blood glucose ❒ Serum electrolytes ❒ Total protein	❒ Chemistry auto-analyzer (or Manual Photometer)
❒ Examination of cerebrospinal fluid (CSF) for yeast	❒ Negative staining-India ink
❒ Examination of CSF, pus, deposit, etc., micro-organisms	❒ Gram stain
❒ Culture	❒ Aerobic ❒ Anaerobic ❒ CO_2
❒ Drug sensitivity	❒ Disc diffusion
❒ Microscopy for plague	❒ Wayson staining
❒ Processing biopsy	❒ Hematoxylin and eosin

Tests Performed at the Regional Hospital Laboratory (continued)	
Laboratory Test	**Standard Technique**
❒ Semen analysis	❒ Microscopy
❒ Cytology	❒ Microscopy ❒ Pulp smear
❒ Sputum for TB	❒ ZN stain
❒ Urine sediment microscopy	❒ Direct microscopy
❒ Urine chemistry	❒ Uristix
❒ Genito-urinary track specimens	❒ Wet prep ❒ Gram ❒ KOH
❒ Blood group, type and cross matching	❒ Tube method
❒ Skin snip for microfilaria	❒ Saline direct
❒ Examination for fungi	❒ KOH
❒ Confirmatory test for syphilis	❒ TPHA

APPENDIX B
LIST OF CONSUMABLES

Consumables Used for a Specific Test	General Consumables
Anaerobic sachets	Alcohol
Bijou bottles	Applicator stick
Blood culture bottles	Autoclave tape
Blood lancets	Cotton wool
Blotting paper	Face masks
Capillary tubes	Filter paper
Centrifuge tubes	Gloves
Cotton swabs	Immersion oil
Cover slips	Lens tissue
Gauze mesh	Lysol
Heparinized capillary tubes	Methylated spirit
Immersion oil	Petri dish (if these are disposable)
Khan tubes	pH paper
Lancet	Printed labels
Microaerophilic sachets	Soap
Microscope slide	Sodium hypochlorite
Microtainer	Xylene
Microtitre plates	
Pipette tips	
Pipette tips (filtered)	
Prepacked iodine swabs	
Printer paper for CBD machine	
Printer paper for CD4/CD8 machine	
Sputum container	
Stool container	
Test tubes	
Universal containers	
Vacutainer, red top	
Vacutainer, grey top	
Vacutainer, EDTA	
Vacutainer needles	
Vacutainer needle holder	

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